Before the
U.S. FEDERAL COMMUNICATIONS COMMISSION
Washington, DC 20554

and the

U.S. FOOD AND DRUG ADMINISTRATION
Silver Spring, MD 20993

In the Matter of Regulatory Issues Arising from Health Care Devices that Incorporate Radio Technology Communications Networks	)	FCC Docket No. ET 10-120 FDA Docket No. FDA 2010-N-291

Philips Healthcare (Philips) is pleased to submit the comments below following up on the joint FCC- FDA public meeting on regulatory issues arising from health care devices that incorporate radio technology in wireless communications networks. Philips is the world leader in patient monitoring equipment and one of the largest suppliers of medical equipment in the United States.

Philips was pleased to have had the opportunity to participate in the recent joint FCC and FDA meeting to address the growing challenges and opportunities presented by the convergence of medical devices integrated with wireless communication technologies. It was evident at the meeting that the medical application of wireless is vast and application needs are quite varied both from the clinical use case perspective and networking performance requirements. Demand for wireless monitoring devices in particular is steadily increasing. A growing number of medical services use wireless devices or applications for physiological monitoring because they provide a higher level of continuous care with better patient outcomes. Philips' wireless monitoring devices blend wired and wireless communications with seamless handoff so that patients can be monitored continuously, even while exercising and moving about.

In response to the Public Notice, Philips respectfully submits the following suggestions for the FDA and FCC to consider when formulating the next steps to unleash the potential innovations that are offered by this technology convergence.

- At the joint meeting differing views on spectrum needs for medical applications surfaced with regard to the use of primary or secondary spectrum versus unlicensed spectrum. In Philips' vast healthcare experience across a large part of this healthcare space we do not find these contradictions unexpected, and in our view these contradictions can be readily addressed with the right industry thought leaders. Philips would like to recognize the proven FCC dictum that the use of spectrum is best determined by the device or application needs. Whether the success of WMTS in healthcare or the clear and vital importance of protecting

incumbent users such as public safety with dedicated spectrum, the precedence is clear – there is no *one size fits all* when it comes to spectrum allocation. Licensed or unlicensed, primary or secondary, whether it be the laws of physics or FCC-defined spectral characteristics, each band of spectrum has specific attributes and limitations that must be considered when defining device and application usage. Certainly the significant number of clinical use cases multiplied by the varied medical applications and devices soon to be available will not be well served by a single use of general purpose licensed *or* unlicensed spectrum. This is especially true in the case of healthcare where ensuring patient safety and data security are paramount. Wireless connectivity in healthcare demands effective application of spectrum employing technologies appropriate for primary and secondary use for medical devices. This is critical to the successful adoption of the cost reducing healthcare initiatives identified in chapter 10 of the FCC's National Broadband Report.

- New applications, such as MBAN for body worn sensors, fit well within the scope of the FCC's Broadband plan as "the last few feet of communication" to collect patient data. The efficient collection and monitoring of patient data with advanced analysis algorithms is a vital aspect of reducing healthcare cost. The proposed MBAN solutions will achieve high levels of spectrum efficiency, an important consideration when using scarce spectrum resources. The proposed allocation in the 2.3 GHz band provides a unique opportunity to leverage commercially available radios at very low cost, a critical aspect to expanding a higher level of care to more patients. (Philips Healthcare filed detailed Comments and Reply Comments addressing spectrum for MBANS in FCC ET Docket No. 08-59.) The FCC should consider the MBAN allocation as part of the national broadband strategy with the specific limitation for shared medical use on a secondary basis. Furthermore, this should be recognized as part of the government spectrum contribution to allow the FCC to accomplish its vision of enabling wireless healthcare devices.

- The FDA should consider publicly recognizing IEC 80001-1 regarding guidance for hospital and healthcare medical IT-networks as well as developing a strong partnership with JCAHO to help drive the adoption of IEC 80001-1 as part of a hospital medical IT-network risk management process. The IEC 80001-1 and accompanying Technical Reports is a voluntary standard with guidance that provides a framework for the development of safe, effective and secure Medical IT-Networks. FDA recognition would drive healthcare institutions to put in place the infrastructure needed to safely and effectively support the use of medical devices on hospital wired and wireless networks. The application of this standard to WWAN networks also should be considered such as in the case of smart phones on cellular networks.

- With regard to reliability, spectrum, and risk, advanced radio technologies are available that allow the safe use of secondary as well as primary spectrum allocations. In this regard, Philips notes that for many years wireless medical

devices have safely used secondary spectrum allocations and more recent primary allocations complement but do not replace this use.

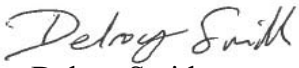
- With regard to interference and coexistence, some argue for more testing. However, this approach is impractical given the vast variety of medical devices. Instead, well defined interface specifications should be adopted to achieve coexistence. The testing then would be to test against interface specifications. Similarly, for EMC considerations the appropriate EMC standards should be kept current to address new devices and technologies. The FDA should encourage the development of EMC standards to account for new medical technologies in development (products that use technologies not previously used in health care facilities) to assess their potential for interference with existing medical devices.

- Philips also welcomes the pending release of the FDA wireless guidance document. Its release in final form will help foster stronger awareness in this area and lend more regulatory certainty to the wireless device approval process.

- Philips recommends that the energy gained with the recent meeting be shepherded into the timely formation of workgroups or workshops to specifically address the above issues. These workshops should have clear objectives and deliverables outlined, and include all stakeholders from both the regulatory and public and private sectors of the healthcare and wireless industry.

Philips is pleased to provide these comments and looks forward to participating in future meetings or workshops to help address and clarify these and other regulatory issues related to medical devices that use wireless and/or broadband technologies.

Respectfully,



Delroy Smith
Engineering Project Leader
PHILIPS HEALTHCARE
3000 Minuteman Road
Andover, MA 01810

Respectfully,

David R. Siddall
Counsel to Philips Healthcare
SONNENSCHEIN NATH & ROSENTHAL LLP
1301 K Street NW, Suite 600 East
Washington, DC 20005

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sense and simplicity

Current state of wireless health and lessons learned:

Advancing patient care with innovation in wireless connectivity

26 July 2010 Dale Wiggins, Chief Technology Officer

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Key products and services of Philips Healthcare

Providing comprehensive support

Philips Healthcare

Businesses

Imaging Systems	Home Healthcare Solutions	Patient Care and Clinical Informatics	Services
			
Interventional X-Ray Diagnostic X-Ray CT MR SPECT/CT PET/CT Ultrasound Women's health	Sleep disordered breathing Respiratory care Home monitoring	Patient monitoring Clinical informatics Cardiac resuscitation ECG solutions Ventilation	Site planning and project management Ambient experience Education Performance services Maintenance

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Inside the Healthcare Facility

Ambulatory & Wireless Patient Monitoring: Why Wireless?

- Enables freedom of movement for patients, which speeds recovery and minimizes complications
- Provides immediate access to patient data for mobile Care givers
- Improves recognition and response to changes in a Patient's condition
- Enables immediate and seamless integration of patient data into EMR and Clinical Decision Support Systems
- Facilitates goal of monitoring every hospital patient seamlessly from ER to discharge and lowers cost of care

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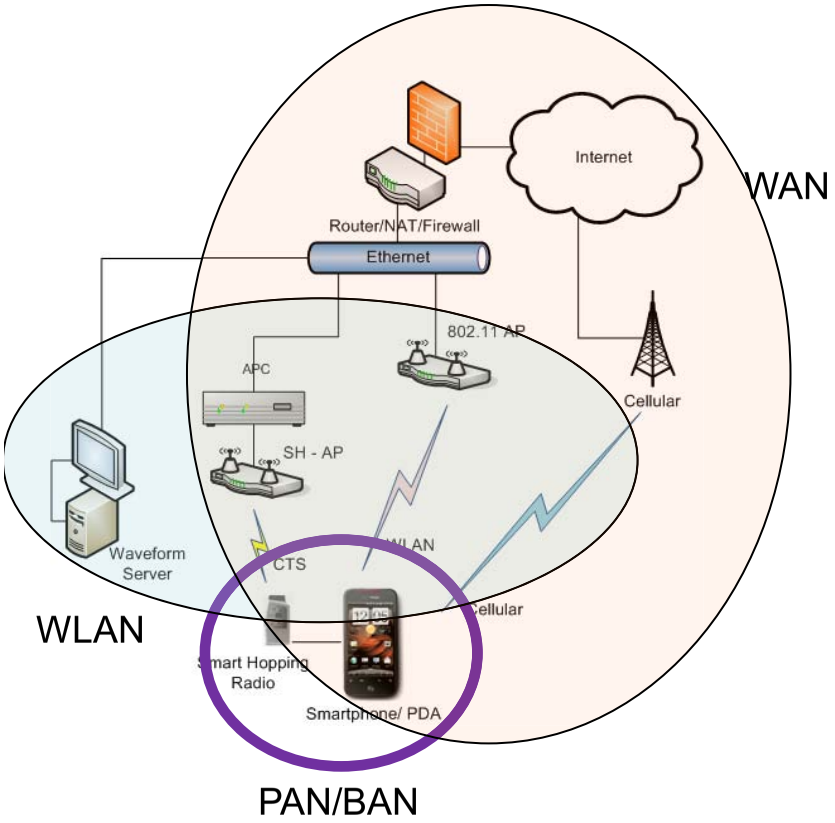
Extending Outside the Healthcare Facility

It's Complicated…



- Health and Well Being in the home
  - From exercise tracking to medical alerting services
- Monitoring in assisted living centers
  - From motion and temperature sensors to nurse call systems
  - Remote video consulting
- Smart phone medical applications over WAN/Wi-Fi links

Wireless solutions are systemic in nature…

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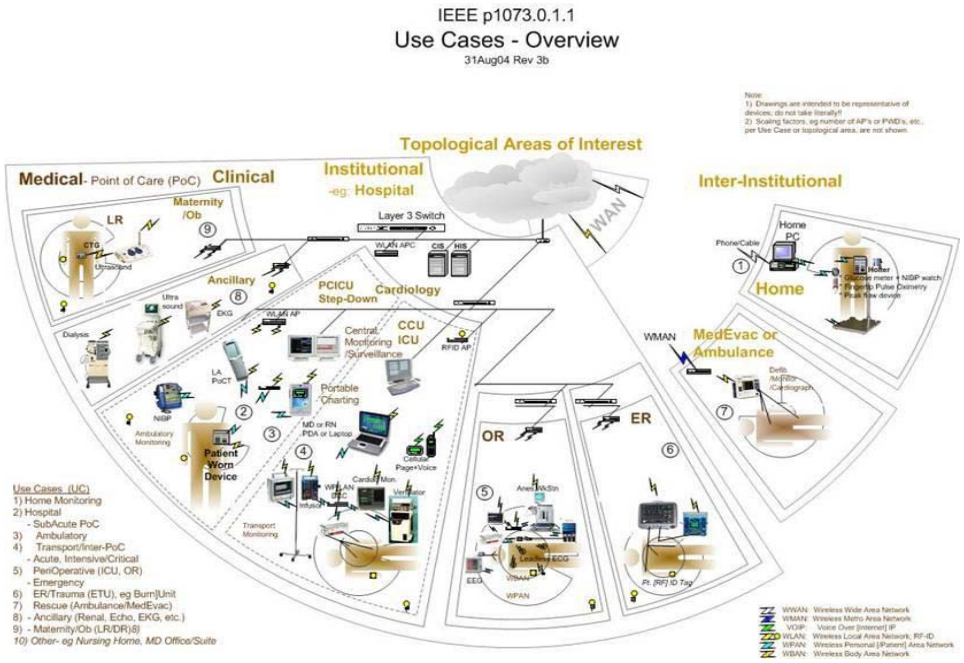
The wireless needs of healthcare are expanding

. . . Many types of devices to meet demand from variety of use models



Multitude of DEVICES

- Telemetry & sensors need long battery life & lower data rate solutions
- Wireless bedside devices demand higher data rate solutions
- Application servers and databases

Variety of Use MODELS

- Primary monitoring, e.g. telemetry, and bedsides
- Secondary support monitoring, e.g. wireless bedsides to central station
- Intermittent monitoring, e.g. vital signs monitoring

- These models cannot be satisfied by one wireless solution
  - Primary protected spectrum
  - Secondary shared spectrum
  - Unlicensed ISM spectrum
  - Safety coexistence mechanisms

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Conclusion…One size does not fit all

- Wireless use of medical devices is exploding
  - Hospital: Use of Wi-Fi in hospitals grew 60% last year*
  - Home: Interoperable personal healthcare solutions (continuaalliance.org)
  - Physician: Smart phones and tablet PC's

- Multiple wireless modalities of connectivity needed to meet multiple demands
  - Primary protected spectrum (WMTS)
  - Secondary shared spectrum (MBANS, WMTS proposals)
  - Unlicensed shared spectrum (Wi-Fi, smart hopping, etc.)
  - Licensed spectrum (WiMax, 3G, LTE)

- Challenges with today's technologies and approaches
  - 4G/LTE/WiMax must share spectrum with voice and data devices
  - Secondary use of idle spectrum, requested but not always granted
  - FCC Part 15 "must accept interference and capacity limitations"
  - Poorly defined shared authority for operation and safety of wireless medical devices

*http://www.ama-assn.org/amednews/2010/07/12/bisb0712.htm

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Solutions…

Improve patient care and protect safety by encouraging innovation and providing sufficient spectrum

- FCC should allocate more spectrum to meet growing demand for wireless medical devices; doing so would improve patient care and provide seamless data into electronic health records (EHRs)
  - Allocate more spectrum for secondary use, including WMTS at 1.4 GHz and MBANS at 2.3 GHz
  - Settle 'White Space" reconsideration petitions to remove current uncertainty and promote investment
  - Rule on spectrum request for use by implanted devices

- Cognitive radio technologies dynamically adapts to the changing RF environment with spectrum sensing, analysis and decision making allows for safe and effective use of secondary spectrum

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Solutions (cont.) …

- FCC and FDA should draft and adopt joint memorandum of understanding concerning wireless devices to clarify FCC's jurisdiction over wireless medical spectrum matters and FDA's jurisdiction over wireless medical spectrum safety

- FDA should finalize and release draft wireless guidance for safety of wireless medical devices

- FDA and FCC should organize industry experts work-shops/groups and define support for applicable voluntary standards (IEC 80001-1)